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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,025	07/31/2001	Neill B. Walsdorf SR.	HO-P02490US0	3707

26271 7590 11/03/2003

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	14

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/919,025	Applicant(s) WALSDORF ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communicati n appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "medicinal" in claims 1,7 does not appear to have antecedent basis. Examiner suggests "pharmaceutical". The term "single dose" in claims 13, 19, 25 does not appear to have antecedent basis.

Claims 1, 7 are objected to because of the following informalities: "compososition" should be "composition".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1-32 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 13 filed 8/11/2003. In that paper, applicant has stated "the presence of additional calcium salts in a composition neutralizes the gastric juice and inhibits the solubility of other calcium salts", and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not exclude other calcium salts.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13,14,18,19,20,25,26,27,28,32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over CN 1210695.

CN 1210695 expressly discloses water which is mineralized with calcium glutarate for drinking falling within the scope of applicant's claims (Abstract).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978); Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd -Pat. App. & Inter. 1993).

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not

depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The rejected method claims do not appear to depend on the preamble for completeness as the body of the claims merely indicate that an amount is to be administered to a mammal or person. Further, an amount defined by its intended use is still an amount and Applicant is required to show that the amount recited in the prior art would not fall within said amounts.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the limitation "a single dose" is by definition intended to be consumed within a limited time period. As such, the Applicant argues that this limitation avoids the prior art. However, no where in the Specification is the limitation "a single dose" defined. As such, the Specification does not define any time period or amount which is contained in the limitation "a single dose". As such, Applicant has not shown that the limitation avoids the prior art.

Claims 13-20,25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over RO 87637 in view of CN 1210695 and Remington's.

RO 87637 teaches a composition which comprising calcium glutarate which is used as a medicinal (Abstract).

CN 1210695 teaches that calcium glutarate is suitable for use in drinking water (Abstract).

Remington's teaches that pharmaceutical preparations can be prepared as liquids, gelatin capsules or tablets as desired and that with respect to tablets, evolution of carbon dioxide is an effective way to cause disintegration of compressed tablets (Pgs. 1492,1603,1607,1625).

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The rejected method claims do not appear to depend on the preamble for completeness as the claims merely indicate that an amount is to be administered to a mammal or person without indicating that they are in need thereof. Further, an amount defined by its intended use is still an amount and Applicant is required to show that the amount recited in the prior art would not fall within said amounts.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose administration of calcium glutarate during mealtime, in tablet form, in gelatin capsule form, in effervescent form. However, the prior art amply suggests the same as it is known that calcium glutarate is suitable as use as a medicinal and for providing minerals and methods of preparing pharmaceutical dosage forms are known in the art. As such, it would have been well within the skill of and one ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the calcium glutarate would be administratable by dosage forms known in the art, including, in tablet, gelatin capsule,

effervescent and liquid form, and that various amounts could be used, including amounts falling with the claimed amounts, as desired to provide sufficient medicinal effect and/or minerals to persons and/or mammals.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Contrary to Applicant's arguments, as indicated above, Examiner has set forth the motivation to combine the references. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., not using other calcium salts) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that there is no motivation to create a composition with multiple calcium salts as they would neutralize the gastric environment, thus causing the possible need for an increased calcium glutarate dose. However, the prior art already expressly discloses a mixture of calcium salts including calcium glutarate (See RO 87637), as such, the motivation to create a composition with multiple calcium salts is not at issue. Further, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Applicant argues that the combined references to not teach a single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract. However, as indicated above, the limitation "single dose" is not defined in the Specification or the claims and, thus, does not appear to avoid the prior art. Further, the limitation "sufficient to bind with phosphorous in the gastrointestinal tract" defines a range of

amounts which have not been shown to avoid the prior art. As such, Applicant has not shown that the limitations above avoid the prior art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC
October 25, 2003

S. MARK CLARDY
PATENT EXAMINER
GROUP 1616